KUH P01 Pre-review Guidelines

The National Institute of Diabetes, Digestive, and Kidney Diseases has recently undertaken a review of its policy concerning Program Project Grants (P01s). This review prompted the Division of Kidney, Urologic, and Hematologic Diseases to establish the following guidelines to be used in the administrative review of applications prior to submission. The purpose of the administrative review is to ensure optimal use of the P01 grant mechanism to fund collaborative, interdependent programs that would suffer if the individual projects were funded via the R01 mechanism.

- 1) Investigators who wish to submit a new P01 application should contact the relevant Program Director approximately 1 year before the anticipated application submission date to discuss the potential application and its relevance to NIDDK's mission.
- 2) At least 6 months prior to application submission, investigators must submit a letter of intent for all applications new, renewal, and resubmission which must be approved by NIDDK staff before the application will be accepted for review. The letter of intent should contain the following items:
 - A summary of the broad problem that is to be addressed by the group
 - Summaries of each individual project
 - A statement of how the projects will interact in an interdependent way to move the field forward. If the application is a competitive renewal, the letter should provide concrete examples of the interdependence of the projects, e.g., examples of how work in one project has catalyzed research in the other groups, how the groups work together on specific questions, how expertise is shared between groups.
 - A description of the core services and how each group will benefit from the core(s).
 - Biosketches of all the project leaders, including other support
 - Proposed percent effort of the PI and Project Leaders
 - For renewals, a list of publications that derived from the P01
- 3) The following criteria will be used in the staff review of the letters of intent:
 - Importance of topic area to NIDDK mission
 - Synergy between projects: How are the groups interdependent? How will the P01 mechanism facilitate research that separate R01s would not? How are scientific projects integrated?
 - Leadership: Strong scientific leadership by the PI is a crucial component of a successful P01. In general, the PI will be expected to devote 25% total effort to the P01, with at least 15% devoted to leadership of the entire program. The individual project leaders are expected to be established, independent investigators who bring valued scientific strengths to the program. The project leaders will generally have independent R01 support.
- 4) <u>All</u> projects should be submitted simultaneously as R01 applications. For renewal applications, projects that were not submitted as R01s will not be eligible for bridge

funding. The R01 budgets may include a component for core support, reflecting the proportion of the P01 core budget that that project would require.

5) The NIDDK program officer may arrange a conference call between the PI, KUH staff, and NIDDK review staff to clarify any of the above issues and to facilitate the application process.